UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

R.S.B., a minor, by and through his Parent and Next Friend, Stephanie Hammar, and STEPHANIE HAMMAR, Individually,

Plaintiffs,

v. Case No. 20-C-1402

MERCK & CO., INC. and MERCK SHARP & DOHME CORP.,

Defendants.

DECISION AND ORDER GRANTING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

Plaintiffs R.S.B., a minor, by and through his parent and next friend, Stephanie Hammar, and Stephanie Hammar, individually, brought this action against Defendants Merck & Co., Inc., and Merck Sharp & Dohme Corp. (collectively Merck), alleging that R.S.B.'s use of Merck's product, Singulair®, caused him to suffer neuropsychiatric injuries. Plaintiffs assert claims of strict liability design defect, strict liability failure to warn, and negligence. The Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332. Before the Court is Merck's motion for summary judgment on Plaintiffs' strict liability and negligent failure to warn claims. Dkt. No. 75. For the following reasons, the motion will be granted.

BACKGROUND

Singulair, generally known as montelukast, is a prescription medication that was originally approved by the FDA on February 20, 1998. Defs.' Statement of Fact (DSOF) ¶ 20, Dkt. No. 78.[1]

[1] Plaintiffs have not filed a "concise response to the moving party's statement of facts" as is required by Civil Local Rule 56(b)(2)(B). Therefore, the Court will deem Merck's

It is indicated for the "prophylactic and chronic treatment of asthma in adults and pediatric patients six years and older." *Id.* R.S.B. was prescribed Singulair from approximately December 2010 to August 2012 for the purpose of treating asthma and hay fever symptoms. 2d Am. Compl. ¶ 7, Dkt. No. 29. Plaintiffs allege that, as a direct and proximate result of ingesting Singulair, R.S.B. was admitted to a psychiatric inpatient facility for suicidal and homicidal thoughts, and was diagnosed with "Major Depressive Disorder, Anxiety Disorder, Obsessive-Compulsive Disorder, Ego-Dystonic and Intrusive thoughts about Homicidal, Suicidal, and Sexual thoughts, and Poor Coping." *Id.* at ¶ 8.

On the date R.S.B. began using Singulair, a variety of warnings appeared on its labeling. First, it warned that "[n]europsychiatric events have been reported with SINGULAIR. Instruct patients to be alert for neuropsychiatric events. Evaluate the risks and benefits of continuing treatment with SINGULAIR if such events occur." DSOF ¶¶ 62–63. A second warning reiterated the reporting of neuropsychiatric events but provided more detail: "Post-marketing reports with SINGULAIR use include agitation, aggressive behavior or hostility, anxiousness, depression, disorientation, dream abnormalities, hallucinations, insomnia, irritability, restlessness, somnambulism, suicidal thinking and behavior (including suicide), and tremor." *Id.* at ¶ 64. That portion of the label further remarked that the "clinical details of some post-marketing reports involving SINGULAIR appear consistent with a drug-induced effect." *Id.* These specific events were again listed in the "Post-Marketing Experience," "Patient Counseling Information," and "Patient Information Sheet" sections of the label. *Id.* at ¶¶ 65–67.

Plaintiffs allege that, despite the warnings described above, Merck "failed to provide adequate warnings of the dangers regarding the fact that Singulair® ingestion increased the risk

"uncontroverted statements of material fact admitted solely for the purpose of deciding summary judgment." Civil L.R. 56(b)(4).

[of] suffering from neuropsychiatric events." 2d Am. Compl. ¶ 105. They further allege that Merck negligently failed to "adequately warn Minor Plaintiff, Plaintiff, physicians, users/consumers, and the general public that Singulair®'s risk of harm was unreasonable and that there were safer and effective alternative medications available." *Id.* at ¶ 130. Importantly, these are state-law claims, and Merck seeks summary judgment on the ground that the claims are preempted by federal law.

LEGAL STANDARD

Summary judgment is appropriate when the movant shows that there is no genuine issue of material fact and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). In deciding a motion for summary judgment, the Court must view the evidence and make all reasonable inferences that favor them in the light most favorable to the nonmoving party. *Johnson v. Advocate Health & Hosps. Corp.*, 892 F.3d 887, 893 (7th Cir. 2018) (citing *Parker v. Four Seasons Hotels, Ltd.*, 845 F.3d 807, 812 (7th Cir. 2017)). The party opposing the motion for summary judgment must "submit evidentiary materials that set forth specific facts showing that there is a genuine issue for trial." *Siegel v. Shell Oil Co.*, 612 F.3d 932, 937 (7th Cir. 2010) (citations omitted). "The nonmoving party must do more than simply show that there is some metaphysical doubt as to the material facts." *Id.* Summary judgment is properly entered against a party "who fails to make a showing to establish the existence of an element essential to the party's case, and on which that party will bear the burden of proof at trial." *Austin v. Walgreen Co.*, 885 F.3d 1085, 1087–88 (7th Cir. 2018) (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986)).

ANALYSIS

"The Supremacy Clause invalidates state laws that interfere with, or are contrary to, federal law." *Dolin v. GlaxoSmithKline LLC*, 901 F.3d 803, 811 (7th Cir. 2018) (internal quotation marks and citations omitted). State law includes "state common law or state statutes that require drug

manufacturers to warn drug consumers of the risks associated with drugs." *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1672 (2019). The form of federal preemption at issue here, called conflict or impossibility preemption, "occurs when there is 'an actual conflict between state and federal law such that it is impossible for a person to obey both.'" *Dolin*, 901 F.3d at 811 (quoting *Guilbeau v. Pfizer, Inc.*, 880 F.3d 304, 310 (7th Cir. 2018)). Where this is true, "federal law controls and the state-law tort claims must be dismissed." *Id.* The question of preemption is "one for a judge to decide, not a jury." *Albrecht*, 139 S. Ct. at 1672.

The federal law that the Court is to consider is the "statutory and regulatory scheme through which the FDA regulates the information that appears on brand-name prescription drug labels." *Id.* "[P]rospective drug manufacturers work with the FDA to develop an appropriate label when they apply for FDA approval of a new drug." *Id.* at 1673 (citing 21 U.S.C. §§ 355(a), 355(b), 355(d)(7); 21 C.F.R. § 314.125(b)(6)). Because information about drug safety may change over time, drug manufacturers may "seek advance permission from the FDA to make substantive changes to their drug labels." *Id.* However, the "changes being effected" or "CBE" regulation, "permits drug manufacturers to change a label without prior FDA approval if the change is designed to 'add or strengthen a . . . warning' where there is 'newly acquired information' about the 'evidence of a causal association' between the drug and a risk of harm." *Id.* (citing 21 C.F.R. § 314.70(c)(6)(iii)(A)). The term "newly acquired information" is defined as:

> data, analyses, or other information not previously submitted to the Agency, which may include (but is not limited to) data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data (e.g., meta-analyses) if the studies, events, or analyses reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA.

21 C.F.R. § 314.3(b).

The CBE regulation is important here because "[s]tate laws requiring a label change are preempted unless the manufacturer could unilaterally add the new warning under the CBE

regulation." *Dolin*, 901 F.3d at 814 (citing *Wyeth v. Levine*, 555 U.S. 555, 573 (2009); *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 620 (2011)); *accord Knight v. Boehringer Ingelheim Pharm., Inc.*, 984 F.3d 329, 337 (4th Cir. 2021) ("A state law challenge to FDA-approved warnings, including a tort action under state law, can thus proceed only when the defendant had the unilateral ability to change that labeling; otherwise, the claim is preempted."). But even if a manufacturer could unilaterally add the new warning under the CBE regulation, preemption nonetheless exists if there is "clear evidence that the FDA would have rejected the proposed change in the drug's label." *Dolin*, 901 F.3d at 812 (internal quotation marks and citation omitted). As one court succinctly stated:

> In sum, impossibility preemption exists (because federal law makes it impossible to comply with state laws) if (1) the manufacturer has no "newly acquired information" that would allow it to invoke the CBE regulations, or (2) attempting to modify the label to reflect this "newly acquired information" would be futile because there is clear evidence that the FDA would not approve the labeling change. *Wyeth*, 555 U.S. at 568. On the other hand, if the manufacturer has "newly acquired information" that allows it to invoke the CBE regulations, and there is no clear evidence that the FDA would disapprove a CBE modification, impossibility preemption does not exist.

Silverstein v. Boehringer Ingelheim Pharm., Inc., No. 19-CIV-81188-Ruiz/Reinhart, 2020 WL 6110909, at *9 (S.D. Fla. Oct. 7, 2020).

Here, the parties dispute whether Merck had "newly acquired information" that would have allowed it to unilaterally change Singulair's label by invoking the CBE regulation. Plaintiffs assert that Merck had two pieces of newly acquired information that would have allowed it to invoke the CBE regulation—a 2009 study that analyzed behavior-related adverse events in clinical trials of montelukast, and a 2011 article, originally published in Chinese, regarding a five-year-old child who experienced adverse events after taking montelukast. Dkt. No. 79 at 4–7. The Court will address each in turn.

Plaintiffs point to a study published in 2009, entitled "Analysis of behavior-related adverse experiences in clinical trials of montelukast." Dkt. No. 81-1. The study concludes that "[r]eports of [behavior-related adverse experiences] were infrequent in clinical trials of montelukast. Those leading to study discontinuation or considered serious were rare. Frequencies were similar regardless of treatment group." *Id.* at 1. Plaintiffs assert that the study's conclusions are flawed because they (1) ignore a large increase in montelukast-treated patients that developed depression, irritability, sleep disorders, and mood disorders; (2) improperly aggregated neuropsychiatric effects, such as depression and anxiety, with unrelated adverse effects, such as fatigue and irritability; and (3) improperly reported statistical differences between the montelukast group and the placebo group, as opposed to reporting statistical differences between the montelukast group and active control group. Dkt. No. 79 at 4–5. A "more scientifically rigorous analysis" of the adverse events observed during clinical trials, Plaintiffs claim, would have identified a larger association between neuropsychiatric events and montelukast treatment, thus allowing Merck to invoke the CBE regulation utilizing this newly acquired information. *Id.* at 5.

Plaintiffs' arguments on this issue must be rejected. First, the supposed flaws detected by Plaintiffs are wholly unsupported by the record. Plaintiffs rely on an opinion from Dr. Dima M. Qato, who provided them with the three identified flaws and opined that a more rigorous analysis would have identified a larger association between neuropsychiatric events and montelukast in younger age groups. *See* Pls.' Statement of Fact (PSOF) ¶¶ 1–2, Dkt. No. 81. But as presented to the Court, Dr. Qato's opinion can be afforded no weight because Dr. Qato's findings are not found in a declaration, affidavit, or any other sworn document. Indeed, Dr. Qato's opinion is only recounted in a block quote in Plaintiffs' statement of fact. *Id.* That block quote is unaccompanied by any citation to the record, effectively requiring the Court to take Plaintiffs' word that Dr. Qato made these findings and that the findings are adequately supported by scientific analysis. Civil

Local Rule 56(b)(2)(B)(ii) requires Plaintiffs to include "references to the affidavits, declarations, parts of the record, and other supporting materials relied upon to support the facts described in that paragraph." Plaintiffs have not done so, and therefore, Dr. Qato's opinion can be afforded no weight.

Second, even were the Court to consider Dr. Qato's opinion, her conclusions are litigation-driven and unsupported by any published research, and therefore do not constitute newly acquired information. *See In re Incretin-Based Therapies Prods. Liab. Litig.*, 524 F. Supp. 3d 1007, 1024–25 (S.D. Cal. 2021), *aff'd*, No. 21-55342, 2022 WL 898595 (9th Cir. Mar. 28, 2022) ("Additionally, to the extent Plaintiffs argue that their expert's re-analysis of the slide images finding PanINs in exenatide-treated animals amounts to newly acquired information, the Court disagrees. This expert report was generated in preparation for litigation and is not supported by published research." (internal citations omitted)); *see also R.S.B. v. Merck & Co., Inc.*, No. 20-C-1402, 2021 WL 6128161, at *4 (E.D. Wis. Dec. 28, 2021) ("Plaintiffs are not entitled to create their own 'newly acquired information' through the use of experts.").

Finally, Plaintiffs attempt to shift the burden to Merck by arguing that it could have undertaken the same analysis that Dr. Qato did, and that, had it done so, it would have had information that allowed it to invoke the CBE regulation. Dkt. No. 79 at 17–26. But this burden-shifting argument "upends" the preemption framework laid out by the various Courts of Appeal and would allow litigants to circumvent it by "merely alleging that a manufacturer should have created the 'newly acquired information.'" *Gayle v. Pfizer Inc.*, 452 F. Supp. 3d 78, 88 (S.D.N.Y. 2020), *aff'd*, 847 F. App'x 79 (2d Cir. 2021). Such an argument cannot stand. Therefore, for the reasons explained above, the Court concludes that Dr. Qato's analysis does not constitute newly acquired information.

Next, Plaintiffs point to a 2011 article, originally published in Chinese, titled "One Case about Mental Disorders Induced by Montelukast." Dkt. No. 81-2. Plaintiffs, with no citation to the record, assert that Merck was in possession of this article by the middle of 2011. The authors of the article discuss the case of a five-year-old boy who was given montelukast to treat asthma and a recurrent cough. *Id.* After being administered montelukast, the boy's asthma and cough improved significantly within two days, but he also began to experience psychiatric symptoms that included "laughing, yelling, nervous excitation, and attacking and biting people." *Id.* Treatment with montelukast was stopped and his psychiatric symptoms resolved. *Id.* After five days, treatment with montelukast was restarted and the psychiatric symptoms reappeared. *Id.* When treatment with montelukast ceased for a second time, the psychiatric symptoms again resolved. *Id.*

Plaintiffs assert that this article constitutes newly acquired information that would have allowed Merck to utilize the CBE regulation to include an additional warning about the potential for neuropsychiatric events in children and adolescents. But the Zhao article does not "reveal risks of a different type or greater severity or frequency than previously included in submissions to" the FDA. 21 C.F.R. § 314.3(b). Plaintiffs make no effort to demonstrate how this single adverse event reveals a risk of a different type or greater severity or frequency than was already warned of at the time the article was published. Indeed, as Merck's uncontroverted statement of fact demonstrates, the label for Singulair in 2011 already listed "agitation, aggressive behavior or hostility, anxiousness, depression, disorientation, dream abnormalities, hallucinations, insomnia, irritability, restlessness, somnambulism, suicidal thinking and behavior (including suicide), and tremor." DSOF ¶ 64. A single report, unaccompanied by any significant analysis, does not demonstrate the existence of a risk that is of a different type or greater severity or frequency, such that a manufacturer can invoke the CBE regulation. *Cf. Gayle*, 452 F. Supp. 3d at 88 ("Courts have also

rejected the notion that analyses based on adverse event reports—much less the reports standing alone—can constitute 'newly acquired information.'"). Thus, the Court concludes that the Zhao article does not constitute "newly acquired information," such that Merck could invoke the CBE regulation.

Because Plaintiffs have failed to demonstrate that Merck had newly acquired information to support a CBE label change, it could not have unilaterally changed Singulair's label. "Consequently, the relevant federal and state laws in this case 'irreconcilably conflict.'" *In re Incretin-Based Therapies Prods. Liab. Litig.*, 524 F. Supp. 3d at 1029 (quoting *Albrecht*, 139 S. Ct. at 1679). Accordingly, Merck's motion for summary judgment based on preemption will be granted.

CONCLUSION

For the foregoing reasons, Merck's motion for summary judgment on preemption grounds (Dkt. No. 75) is **GRANTED**. Plaintiffs' strict liability and negligent failure to warn claims are dismissed. The Clerk is directed to set this matter for a telephone scheduling conference to discuss further proceedings.

SO ORDERED at Green Bay, Wisconsin this 31st day of August, 2022.

s/ William C. Griesbach
William C. Griesbach
United States District Judge